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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/972,425	10/05/2001	Kenneth C. Cundy	033053-025	5701
21839	7590	10/29/2004	EXAMINER	
BURNS DOANE SWECKER & MATHIS L L P			BADIO, BARBARA P	
POST OFFICE BOX 1404			ART UNIT	
ALEXANDRIA, VA 22313-1404			PAPER NUMBER	
			1616	

DATE MAILED: 10/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/972,425

Applicant(s)

CUNDY ET AL.

Examiner

Barbara P. Badio, Ph.D.

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-10 and 18-20 is/are pending in the application.
- 4a) Of the above claim(s) 1,3,4,7,18 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 5,6,8-10 and 19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **Nonfinal Action on the Merits**

#### ***Election/Restrictions***

1. Applicant's election with traverse of Group 117 in the reply filed on August 3, 2004 is acknowledged. The traversal is on the ground(s) that (a) it is improper for the Office to refuse to examine that which Applicants regard as their invention unless the subject matter of the claims lacks unity of invention and (b) unity of invention exists where compounds included within a Markush group share a common utility and share a substantial structural feature. According to applicant, the claimed compounds (a) have a common utility, i.e., they are used as bile acid transport system to provide sustained systemic concentration of orally delivered GABA analogs and (b) comprise a bile acid moiety linked to a GABA analog moiety and that the linker group connecting the bile acid moiety and the GABA analog moiety is not critical. Applicant also argues the present restriction requirement is not in accordance with the Petition Decision dated April 19, 2004 and that Group 117 is narrower than the generic group as defined by the Examiner in the Office Action dated May 2, 2003.

This is not found persuasive because the claimed subject matter lacks unity of invention because that do not share a substantial structural feature that define a contribution over the prior art. According to applicant, the compounds all comprise a bile acid moiety linked to a GABA analog moiety and that the linker group connecting the bile acid moiety and the GABA analog is not critical. However, the issue is not whether the linker is critical to the utility of the compounds but whether the compounds

share a substantial structure feature that defines over the prior art. The linkers defined by the instant claims are important to the structure of the claimed compound. The variation in the linker results in structurally different compounds and, thus, the instant compounds lack unity of invention.

Applicant also argues the present restriction requirement is not in accordance with the Petition Decision dated April 19, 2004. In granting applicant's Petition, it was stated that "no formal restriction requirement has been made". Because the decision was based on the lack of a formal restriction requirement of record, the examiner has now set forth a formal restriction requirement in accordance with the decision dated April 19, 2004.

Lastly, applicant states that Group 117 is narrower than the generic group as defined in the Office Action dated May 2, 2003. Said restriction requirement no longer exists because it was deemed improper based on applicant's petition.

The requirement is still deemed proper and is therefore made **FINAL**.

***Allowable Subject Matter***

2. Claims 5, 6, 8-10 and 19 are objected to as containing nonelected subject matter. Claims directed to compounds of Group 117 including all of the limitations of the base claim and any intervening claims would be allowable.

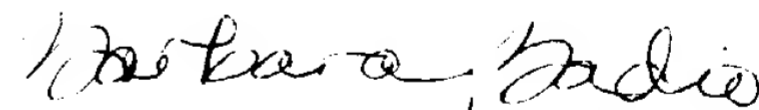
Note: Method claims of the same scope as the allowed compounds will be rejoined and allowed.

***Telephone Inquiry***

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1616

BB  
October 26, 2004